

**RESPONSE UNDER 37 C.F.R. § 1.111
U.S. Application No. 10/574,588 (Q94096)**

REMARKS

This Response, filed in reply to the Office Action dated March 25, 2010, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-12 are all the claims pending in the application. Claims 6-10 and 12 are withdrawn from consideration. Claims 1-5 and 11 are rejected.

Information Disclosure Statement

Applicants thank the Examiner for returning a signed and initialed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed April 4, 2006, indicating consideration of the references therein.

Withdrawn Rejection

Applicants thank the Examiner for withdrawing the rejection of the claims as being unpatentable over Yamazaki *et al.* (US 5,932,178) ("Yamazaki *et al.*") in view of Osaki *et al.* (JP 08-325169) ("Osaki *et al.*") and in further view of Hyodo *et al.* (US 6,827,838 B2) ("Hyodo *et al.*").

I. RESPONSES TO REJECTION UNDER 35 U.S.C. § 103

On page 2 of the Office Action, Claims 1-5 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamazaki in view of Osaki and in further view of Coulter *et al.* (US 2,576,264) ("Coulter *et al.*").

The rejection with respect to the teachings of Yamazaki *et al.* and Osaki *et al.*, is substantially similar to the October 9, 2009, Office Action. In particular, the Office Action acknowledges that neither Yamazaki *et al.* nor Osaki *et al.*, disclose the step of passing carbon

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dioxide through the column. However, the Office Action cites to Coulter *et al.* for a teaching that helium and carbon dioxide are allegedly analogous drying gases/media (column 6, lines 40-45). The Examiner concludes that it would have been obvious to one ordinarily skilled in the art to substitute one inert drying gas, such as the helium of Yamazaki *et al.* for an equivalent inert drying gas, such as carbon dioxide as Coulter *et al.*

Applicants respectfully traverse the rejection. The Office Action has failed to establish a *prima facie* case of obviousness for at least the following reasons. In particular, the Office has failed to establish that one of ordinary skill in the art would not have been motivation to use carbon dioxide gas in the process of Yamazaki *et al.* at least because Coulter *et al.* is a nonanalogous art that would not have been considered by one of ordinary skill in the relevant art. Additionally, analogous art, such as Hyodo *et al.* teaches away from using carbon dioxide gas in a conventional ¹⁸F recovery method due many drawbacks. Furthermore, Applicants respectfully request the Examiner to consider Applicants showing of unexpectedly high production yields of fluorine compound using carbon dioxide gas, when compared to the yields of fluorine compounds produced by the method of Yamazaki *et al.*, which utilizes helium gas.

Coulter *et al.*, a U.S. Patent issued in 1947, is nonanalogous prior art which would not have been considered by a person skilled in the art, in an improvement for producing radioactive-fluoride labeled compound. To rely on a reference under 35 U.S.C. § 103, it must be analogous prior art. As set forth in the Manual of Patent Examining Procedure (“MPEP”), “[t]he examiner must determine what is ‘analogous prior art’ for the purpose of analyzing the obviousness of the subject matter at issue. ‘Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed.’” MPEP Section 2141.01

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(citing *KSR Int'l Co. v. Teleflex, Inc.*). As explained in the MPEP, the reference must have logically commended itself to an inventor's attention in considering his or her invention as a whole. *Id.*

Applicants respectfully submit that Coulter *et al.*, is not such a reference that would have logically commended itself to an inventor developing a process for producing a radioactive-fluoride labeled compound. Rather, Coulter *et al.* discloses an apparatus for *spray drying of food particles*, such as milk or eggs. See Column 1, lines 1-5 (emphasis added). Coulter *et al.* teaches an apparatus wherein the drying media may be recirculated and is concurrent to that of finely divided materials undergoing drying on food. The apparatus of Coulter *et al.* does not utilize an anion-exchange resin and is not used to dry columns which produce radioactive fluoride ions. Thus, contrary to the Examiner's assertions, Coulter *et al.* does not describe "analogous" drying gases/media. The person skilled in the art, considering an improvement for the producing radioactive-fluoride labeled compound would not have looked to Coulter *et al.*. There is no logical rationale for doing so and certainly not one provided in any of the cited documents for combining Yamazaki *et al.* and Coulter *et al.*.

To the contrary, references, previously cited in the October 9, 2009, Office Action, teach away from using carbon dioxide gas. For instance, U.S. Patent No. 6,827,838 to Hyodo *et al.* describes a conventional ¹⁸F recovery method wherein ¹⁸F is separated from ¹⁸O water by ion exchange and then ¹⁸F is recovered by using carbon dioxide gas or potassium carbonate gas. Col. 1, lines 35-50. However, Hyodo *et al.* teaches away from using of carbon dioxide gas, specifically stating that chemicals such as carbon dioxide are "not desirable" due to impurity problems and drawbacks regarding the control of flow rate of a ¹⁸F solvent and the clogging of the ion exchange resin column. Col. 1, lines 44-50. Thus, one of ordinary skill in the art would

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not have been motivated to substitute helium gas, a gas used to dry the column, with carbon dioxide gas, a gas used in a non-analogous food spraying technology, for the purpose of recovering ^{18}F .

Finally, Applicants respectfully request the Examiner to consider Applicant's unexpectedly high production yields of fluorine compound using carbon dioxide gas, when compared to the yields of fluorine compounds produced by the method of Yamazaki *et al.*, which utilizes helium gas. The collection rate using the helium gas as disclosed by Yamazaki *et al.* is low, compared to carbon dioxide. Specifically, Tables 1-3 of the instant application compares the yield of ^{18}F when different resins were used with carbon dioxide gas, helium gas, or nitrogen gas. As shown in Table 1, the yield values using carbon dioxide was high (94.8%) as compared to using helium gas (83.7%) and nitrogen gas (85.9%). Thus, one of ordinary skill in the art would not have expected, nor reasonably predicted, that the gas utilized in the claimed process would produce unexpectedly high yields of fluorine compound, considering the yields disclosed in the art for methods using different gases were significantly lower.

For the foregoing reasons, Yamazaki *et al.*, Osaki *et al.* and Coulter *et al.* do not teach the use of carbon dioxide gas in the process for producing radioactive-fluorine labeled compound. Accordingly, Yamazaki *et al.*, Osaki *et al.* and Coulter *et al* taken alone or in combination, do not teach each and every limitation of Claim 1. For these same reasons, Claims 2-5 and 11 are not rendered obvious by the cited references.

Reconsideration and withdrawal of the rejection under § 103(a) is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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